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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/598,443	06/22/2000	John Ernest Sims	03260.0044	5571

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EXAMINER
HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Rk copy

Office Action Summary

Application No.	Applicant(s)
09/598,443	John Ernest Sims
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 1, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *34-60* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *34-60* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1a. Applicant's election of Group I, in Paper No.10, filed on 01 May 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement is still deemed proper and is therefore made FINAL.

1b. Claims 1-33 have been canceled and new claims 34-60 have been added in Paper No.10, filed on 01 May 2002. Thus claims 34-60 are pending and under consideration.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3a. Claims 48-58 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 48-58 recite ".....a host cell....", which encompasses the cell as it occurs in nature. However, since Applicants do not intend to claim a naturally occurring product, amendment of the claims to show the hand of man would obviate this rejection. It is suggested that claims 48-58 be amended to recite " an isolated host cell.....".

Claim Rejections - 35 U.S.C. § 101/112

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. Claims 34-59 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Instant claims 34-60 are directed to an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:1, and encoding the polypeptide of SEQ ID NO:2 . The nucleic acid of SEQ ID NO:1 is described as bing an isolated SIGIRR (single Ig IL-R related molecule), encoding the SIGIRR polypeptide of SEQ ID NO:2. Instant specification discloses that SIGIRR polypeptide is homologous to members of the IL-1 receptor family, sharing 26% identity to IL-1R type I, 32% amino acid identity to IL-1R AcP, 35% amino acid identity with IL-a RrpI and 33% homologous with TIGIRR, (see page 9, lines 5-10). The polypeptide encoded by the claimed nucleic acid is further described as having a single immunoglobulin extracellular region, a transmembrane domain, a cytoplasmic domain with an extra 100 amino acid at its C terminus compared to IL-1R family members. The specification also states that although SIGIRR is homologous to IL-1R family, the N-terminal domain is predicted to function poorly as a signal peptide, (see page 9, lines 19-22). The specification further discloses that the extracellular domain of SIGIRR polypeptide is unlikely to bind an IL-1 family ligand, and that it may serve as a third component of a signaling complex with IL-R and IL-1R AcP, may bind a soluble ligand that is not an IL-1 family, may bind a molecule on the surface of another cell or associate with some other surface r transmembrane molecule that is not a member of the IL-R family, and that a soluble version of the SIGIRR receptor can be used to inhibit the activities of cytokines to which it binds, (page 9, lines 26-32). One asserted utility for

claimed nucleic acid, is to be used to express the encoded protein. However, beyond disclosing that the human protein encoded by the claimed nucleic acid shares structural homology to known IL-1 receptor family, the specification does not disclose the biological and functional properties of this protein. The specification provides exemplary binding assays (pages 34-36), however, there is no evidence that the SIGIRR protein encoded by the claimed nucleic acid has been tested in these assays, and if so, whether a binding partner has ever been identified for this protein. The specification discloses that IL-1 ligands play a central role in protection against infection and immune inflammatory responses, thus the ligand for SIGIRR, like IL-1α, IL-1β and IL-8 would likely be involved in infection and inflammation, (see page 42, line 26 through page 437). However, since instant specification does not disclose a ligand for the SIGIRR polypeptide encoded by the claimed nucleic acid, the role of the SIGIRR ligand can not be ascertained. Some of the other asserted uses for the claimed nucleic acid are to use it as a probe, and for gene therapy. Firstly, any DNA can be used as a probe, therefore, this use is neither specific nor substantial. Secondly, with respect to the assertion that the claimed nucleic acid can be used in gene therapy, instant specification does not establish a nexus between the claimed nucleic acid and any disease or disorder, thus, it would be impossible to predict which pathological processes might involve the claimed nucleic acid. As a result, it would be impossible for the skilled artisan to use the claimed nucleic acid in gene therapy.

The claimed invention is directed to nucleic acid encoding a receptor of as yet undetermined function or biological significance. Thomassen et al (cytokine, Vol. 11, No:6, June 1999, pages 389-399), teach that SIGIRR may represent a novel subtype of the IL-R superfamily, and although it

possess all of the conserved motifs found in the cytoplasmic domain of the IL-R family, it also contains distinct structural and functional features, (see page 396, column 1). Thomassen et al also disclose that SIGIRR is not part of the IL-1 binding and signaling complex and that it is functionally different from the IL-1R family, (see page 396, bottom of column 2). Thus it appears that the claimed nucleic acid encodes an orphan receptor. There is little doubt that, after further characterization, and once the specific ligand, function and role of the SIGIRR of the instant invention is ascertained, it would have a specific, substantial and credible utility, however, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility. Therefore, there is no specific and substantial or well-established utility for the claimed nucleic acid. The fact that the protein encoded by the claimed nucleic acid might be a member of the IL-1 receptor family is not enough to establish a specific and substantial utility or a well established utility for it.

4b. Claims 34-60 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification only discloses a deduced amino acid sequence for the protein encoded by the claimed nucleic acid. It does not disclose an activity for it, does not disclose a ligand for it, and does not disclose the physiological role of the protein encoded by the claimed nucleic acid, therefore the skilled artisan would not know how to use the nucleic acid having nucleotide sequence set forth in SEQ ID No:1 or the protein encoded by said nucleic acid.

Should Applicants establish an activity for the polypeptide of SEQ ID NO:2 encoded by the polynucleotide of SEQ ID NO: 1, instant specification would still fail to adequately describe and enable an isolated nucleic acid that hybridizes to the nucleic acid of SEQ ID NO:1 and encodes an amino acid sequence that is at least 80% or 90% identical to amino acid 1-118 of SEQ ID NO:2, or a nucleic acid comprising a DNA that is at least 80% or 90 % to the polynucleotide of SEQ ID NO: 1. Applicants do not provide any guidance as to which of the myriad of polypeptide species that share 80% or 90% to the polypeptide of SEQ ID NO:2, from amino acid residue 1 to 118, which are encoded by a polynucleotide that hybridizes to the claimed nucleic acid, will retain the characteristics of the polypeptide of SEQ ID NO:2, therefore, the claims broadly encompass a significant number of inoperative species. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a polynucleotide having at least 80% or 90% sequence identity to SEQ ID NO:1, which encodes the polypeptide of SEQ ID NO:2, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polynucleotide or a polypeptide encoded thereby, other than that exemplified.

In summary, the amount of experimentation required for one of ordinary skill in the art to use the claimed invention an isolated nucleic acid that hybridizes to the nucleic acid of SEQ ID NO:1 and encodes an amino acid sequence that is at least 80% or 90% identical to amino acid 1-118 of SEQ ID NO:2, or a nucleic acid comprising a DNA that is at least 80% or 90 % to the polynucleotide of SEQ ID NO: 1, would be undue. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the

instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those nucleotide sequences of the disclosed naturally-occurring nucleic acid, which are required for functional and structural integrity of the claimed nucleic acid. It is this additional characterization of the disclosed nucleic acid that is required in order to obtain the functional and structural data needed to permit one to produce a nucleic acid which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3-4 and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 59 recites the acronym (TIGIRR), which renders the claim unclear, because it is unclear what the acronym stands for, and more than one protein can be known for the same acronym. Furthermore, there is no antecedent base for TIGIRR. Applicant is advised to recite the full name of the protein corresponding to this acronym to obviate this rejection.

Conclusion

6. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wedensday-Thursdays from 7:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
20 November 2002

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